K102981

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Manufacturer Name: ACE Surgical Supply Co., Inc.
Manufacturer Address: 1034 Pearl St., Brockton, MA 02301
Telephone Number: (508) 588-3100
Fax Number: (508) 523-3140

Date Prepared: October 1, 2010

DEC 20 2010

Official Contact: Carol A. Houts, Director of Compliance

DEVICE NAME:

Device Trade Name: ACE Surgical iMARK™ Internal Hexagon Dental Implant
Device Common Name: Screw Dental Implant

Reason for submission: Not previously marketed in the USA

ESTABLISHMENT REGISTRATION NUMBER:

The Establishment License Number for ACE Surgical Supply Co. Inc. is 1287163.

DEVICE CLASSIFICATION:

Implant, Endosseous, Root-Form, product code, DZE, 21CFR 872.3640.

PREDICATE DEVICES:

ACE Surgical Screw Dental Implant System (K954513)
Zimmer® Tapered Screw Vent Dental Implant (K011028)

INTENDED USE:

The ACE Surgical iMARK™ Internal Hexagon Dental Implant System is designed for use in totally edentulous mandibles or maxillae or as a terminal or intermediary abutment for fixed or removable bridgework. The system can also be used for single tooth restorations. The ACE Surgical iMARK™ Internal Hexagon Dental Implant System uses a two-stage implantation process..

The ACE Surgical iMARK™ Internal Hexagon Dental Implant System is used in indications for oral endosseous implants in the maxilla and/or mandible as part of a functional and aesthetic oral rehabilitation in partial or fully edentulous patients.

The ACE Surgical iMARK™ Internal Hexagon Dental Implant System is compatible with Zimmer® Tapered Screw Vent prosthetics cleared under K011028.

DEVICE DESCRIPTION:

The ACE Surgical iMARK™ Internal Hexagon Dental Implant System is a screw type dental implant system designed with technology established with the ACE Surgical Screw Dental Implant System

(K954513) and the Zimmer® Tapered Screw Vent Dental Implant (K011028). The ACE Surgical iMARK™ Internal Hex dental implant screw raw material is made of Ti-6-AL-4V ELI per ASTM F136 standard and surface treated with resorbable blast media (RBM). The self tapping internal hex implant features tapered external thread geometry consistent with industry standard screw implant fixtures. The implants are provided sterile and sterility is achieved by gamma radiation pursuant to ISO 11137.

PERFORMANCE CHARACTERISTICS:

The following mechanical tests were conducted to support the substantial equivalence of the ACE Surgical iMARK™ Internal Hex to the ACE Screw Dental Implant System (K954513) and the Zimmer® Tapered Screw Vent Dental Implant (K011028): torsional insertion and shear loading and compressive bending and fatigue strength.

EQUIVALENCE TO MARKETED DEVICE:

The ACE Surgical iMARK™ Internal Hexagon Dental Implant is substantially equivalent to the ACE Screw Dental Implant System (K954513) and the Zimmer® Tapered Screw Vent Dental Implant (K011028). The candidate device and the predicate devices have the same intended use and similar technological characteristics. The candidate device and predicate devices are made of titanium alloy and commercially pure titanium. The candidate and predicate devices have comparable roughened surface treatments. The candidate and predicate devices encompass a similar range of physical dimensions such as diameter and length. The candidate and predicate devices are packaged and sterilized by identical methods. Both the ACE Surgical Screw Implant and the ACE Surgical iMARK™ Internal Hex use a 2 stage implantation process. The Zimmer® Tapered Screw Vent utilizes either a one or two stage implantation process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 2 0 2010

Ms. Carol A. Houts
Director of Compliance
Ace Surgical Supply Company Incorporated
1034 Pearl Street
Brockton, Massachusetts 02401

Re: K102981
Trade/Device Name: ACE SURGICAL iMARK™ Internal Hex Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: December 2, 2010
Received: December 2, 2010

Dear Ms. Houts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEC 2 0 2010

Indications for Use

510(k) Number: K102981

Device Name: ACE SURGICAL iMARK™ Internal Hex Dental Implant System

Indications For Use:

The iMARK™ Internal Hexagon Dental Implant System is used in indications for oral endosseous implants in the maxilla and/or mandible as part of a functional and aesthetic oral rehabilitation in partial or fully edentulous patients.

The IMARK™ Internal Hexagon Dental Implant System is designed for use in totally edentulous mandibles or maxillae or as a terminal or intermediary abutment for fixed or removable bridgework. The system can also be used for single tooth restorations. The IMARK™ Internal Hexagon Dental Implant System uses a two-stage implantation process.

The iMARK™ Internal Hexagon Dental Implant System is compatible with Zimmer® Tapered Screw Vent prosthetics.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102981